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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,695	09/30/2003	Robin D. Pierce	7133.US.01	5085

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EXAMINER	
OLSEN, KAJ K	
ART UNIT	**PAPER NUMBER**
1753	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,695	PIERCE ET AL.	
	Examiner	Art Unit	
	Kaj K. Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-16,18 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-16,18 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

2. Claims 1, 3, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilmartin. This reference is being utilized again as a 102 rejection in view of the amendment to the claims. In particular, applicant removed the limitation requiring the enzyme be a dehydrogenase, thereby requiring this 102 rejection again. See paragraph 1 from the 7/24/2006 office action.

3. Gilmartin discloses a biosensor for determining the concentration of an analyte in a liquid samples (col. 3, ll. 7-24) comprising an electrode support D, an arrangement of electrodes C on the electrode support comprising at least a working electrode and a second electrode. See fig. 1. Gilmartin further discloses first and second conductive tracks A leading from the working and second electrodes to electrical contacts associated with these electrodes (col. 2, ll. 61 and 62), and at least one enzyme and mediator incorporated into the electrode ink for the working electrode. See col. 10, ll. 49-55. With respect to the enzyme or enzyme and mediator being in the first conductive track, it would appear that Gilmartin deposits both the conductive track and the working area of the electrodes at the same time. In other words, there is nothing in the disclosure of Gilmartin to suggest that different inks were utilized for the deposition of elements A and C for any given electrode. Hence, Gilmartin would teach the incorporation of the enzyme or enzyme and mediator in the conductive track as well. With respect to the new limitation beginning "wherein the presence", it is unclear how this limitation further defines the structure of

the device. In particular, this new claim language appears to merely recite how one intends to utilize the device and the intended use need not be given further due consideration in determining patentability. However, even if the examiner were to treat this claim language as defining a structural distinction, Gilmartin teaches that the electrons are transferred from the enzyme ($E_O \rightarrow E_R$) to the mediator ($Fe^{2+} \rightarrow Fe^{3+}$) to the working electrode (i.e. the graphite). See fig. 2. In the arguments of 1/25/2007, applicant urges that Gilmartin requires the use of an intermediate hydrogen peroxide. Albeit correct, Gilmartin's use of this intermediate doesn't read free of claim 1 because the claim is constructed with open language (i.e. the device is "comprising" the various limitations). The fact that Gilmartin uses an additional component in the chain of electron transfer doesn't read away from the claim language.

4. With respect to the optional layer of limitation (c), because this layer is optional, it is not required that Gilmartin disclose this feature.

5. With respect to the various dependent claims, see the discussion of these claims and Gilmartin in the office action of 6-29-2005.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 3, 6-16, 18 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman and Gilmartin with or without evidence from Hedenmo et al (Analyst, 121, 1996, pp. 1891-1895) or Karube et al (USP 5,804,047). The addition of evidentiary references was necessitated by the applicant's amendment to the claims.

8. Feldman discloses a biosensor (col. 1, ll. 13-14) having: (a) an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); (b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); (c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and (d) at least one reagent incorporated in the working electrode (col. 21 , ll. 28- 31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38). Feldman does not disclose placing at least one of the enzyme or mediator and the enzyme into the first conductive track. Gilmartin discloses that the enzyme need not be placed over the electrode and conductive track itself, but that the enzyme and the mediator could be incorporated into the ink itself. See col. 10, ll. 49-52. This would appear to obviate the need for multiple coating steps (i.e. a separate coating of the enzyme layer would not be needed). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Gilmartin for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode. With respect to the enzyme and mediator being incorporated into the conductive track itself, Gilmartin would appear to utilize its ink for the deposition of both the working area of the electodes (area C on fig. 1) and the connecting strip portion (area A of fig. 1). See also the discussion from the non-final office action of 6-29-2005.

9. With respect to the new limitation specifying the particular electron transfer cycle, this new limitation doesn't further define the structure of the device and merely constitutes the intended use of the device. However, even if the examiner were to interpret this new limitation as being a structural feature of Feldman in view of Gilmartin, the teachings of Hedenmo and Karube evidence that the electron cycles for both glucose oxidase and glucose dehydrogenase read on the defined cycles. In particular, fig. 1 of Hedenmo shows for a glucose dehydrogenase-mediator system that electrons are being transferred from the enzyme to the mediator and to the working electrode. Karube shows for a glucose oxidase mediator electrode like Feldman that electrons are transferred from the enzyme to the mediator to the electrode. See the reaction diagram in col. 5.

10. With respect to the optional layer of limitation (c), this layer is not required.

11. With respect to the various dependent claim limitations, see the discussion of Feldman and these limitations in the office action of 6-29-2005.

12. Claims 1, 3, 10, 12, 13, 15, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes in view of Gilmartin with evidence from Karube and alternatively in further view of Feldman with evidence from Hedenmo. The use of Feldman only in the alternative was necessitated by the removal of dehydrogenase from the claims. The use of Karube and Hedenmo as evidence was necessitated by the new limitations of the claims.

13. Hughes discloses a biosensor (col. 1, ll. 5-6) having (a) an electrode support (col. 2, l. 10 and Fig. 1, 1); (b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 2, ll. 11-12 and Fig. 1, 4, 5 and 5a); (c) a first conductive track leading from the working

electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 1 , 2).; and (d) at least one reagent incorporated in the working electrode (col. 4, ll. 28- 29) comprising an enzyme and a mediator (col. 4, ll. 40-42). Hughes does not disclose placing at least one of the enzyme or mediator and the enzyme into the first conductive track. Gilmartin discloses that the enzyme need not be placed over the electrode and conductive track itself, but that the enzyme and the mediator could be incorporated into the ink itself. See col. 10, ll. 49-52. This would appear to obviate the need for multiple coating steps (i.e. a separate coating of the enzyme layer would not be needed). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Gilmartin for the biosensor of Hughes so as to obviate the need for multiple coating steps for the electrode. With respect to the enzyme and mediator being incorporated into the conductive track itself, Gilmartin would appear to utilize its ink for the deposition of both the working area of the electodes (area C on fig. 1) and the connecting strip portion (area A of fig. 1). See also the discussion from the non-final office action of 6-29-2005. With respect to the new limitation drawn to the electron transfer cycle, this limitation merely constitutes the intended use of the device and doesn't further define the structure of the invention. However, even if the examiner were to interpret this limitation as being a structural limitation, Karube evidences that a glucose oxidase (the enzyme relied on by Hughes) inherently has an electron cycle that meets this new limitations. See col. 5 and the discussion above.

14. Alternatively, even if the examiner were to interpret this new limitation as being a structural feature and that this structural feature requires an enzyme such as dehydrogenase, then

it is noted that Hughes doesn't place any criticality on the use of glucose oxidase, but rather stated only that the enzyme was the preferred choice. See col. 4, ll. 42-46. The previously relied on Feldman disclosed that biosensors can be configured to monitor glucose by relying on either glucose oxidase or glucose dehydrogenase. See col. 24, ll. 24-27. Fig. 1 of Hedenmo shows for a glucose dehydrogenase-mediator system that electrons are being transferred from the enzyme to the mediator and to the working electrode. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Feldman for the biosensor of Hughes and Gilmartin because the substitution of one known enzyme for another known and analogous enzyme requires only routine skill in the art.

15. With respect to the optional layer of limitation (c), this layer is not required of the prior art.

16. With respect to the various dependent claim limitations, see the discussion of Hughes and these limitations in the office action of 6-29-2005.

Response to Arguments

17. Applicant's arguments filed 1-25-2007 have been fully considered but they are not persuasive. Applicant urges that Feldman does not disclose the use of an enzyme in a conductive track. However, the examiner rebutted this argument at length in the 7-24-2006 office action (see paragraph 14).

18. Applicant also urges that Gilmartin relies on a hydrogen peroxide measurement system. However, as the examiner has discussed above in the new 102 rejection, the Gilmartin system reads on the system defined by the claims because (a) the electron transfer process of the claims

is only the intended use of the apparatus, and (b) the electron transfer process of Gilmartin still reads on the defined electron transfer process as defined because applicant is using open language to define the process.

19. With respect to the Feldman and Gilmartin rejection, applicant also urges that the examiner is engaging in a piecemeal reconstruction of the prior art (applicant presumably meant --present invention-- and not "prior art"). The examiner disagrees. Gilmartin taught that one could either deposit the enzyme onto the surface of the electrode (like Feldman did) or could mix the enzyme into the actual electrode starting materials when the use of an enzyme layer is not desired. Compare col. 9, ll. 42-46 with col. 10, ll. 49-57. Hence, these two configurations were deemed to be analogous to each other. Moreover, Gilmartin stated that doing the later (i.e. mixing the enzyme into the electrode) obviates the need for a separate attachment step. See col. 10, ll. 59-61. Hence, one possessing ordinary skill in the art would have been motivated for relying on the second configuration of Gilmartin for the device of Feldman because the configuration utilized by Feldman (which is equivalent to the first Gilmartin configuration) and the second configuration were deemed to be analogous to each other and the second configuration obviates the need for multiple coating steps and the need for an attachment means for the additional enzyme layer. There is nothing in this discussion of Gilmartin that is enzyme specific and any differences between the enzyme cycle of Feldman and the enzyme cycle of Gilmartin would be irrelevant to the issue of whether one relied on the second configuration of Gilmartin for the electrode construction of Feldman. The only distinction between the two electrode configurations of Gilmartin is whether the enzyme for the electron cycle is present as a second separate layer or is incorporated into the electrode itself. Whether or not the enzyme

were an oxidase or a dehydrogenase would appear to be irrelevant. Even Feldman recognized that both oxidase and dehydrogenase enzymes are interchangeable with its sensor. See col. 24, ll. 26-29.

20. Applicant's arguments concerning the rejection with Hughes in view of Gilmartin and Feldman appear to parallel those arguments made above for Feldman in view of Gilmartin and arguments made in a previous response. The examiner addressed the supposed deficiencies of Feldman in view of Gilmartin above and in paragraphs 14 and 15 from the 7-24-2006 office action.

21. The examiner has withdrawn the 103 rejections relying on Gilmartin in view of Feldman because Gilmartin is drawn to construction of a hydrogen peroxide electrode and the dehydrogenase of Feldman would not produce hydrogen peroxide.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
April 11, 2007

KAJ K. OLSEN
PRIMARY EXAMINER